FTS-CDC-PHPPO

February 24, 2005
12:00 p.m. CST

Coordinator — Welcome, and thank you all for standing by. At this time, all participants are in a listen-only mode. After the presentation, we will conduct a question and answer session. Today's conference call is being recorded. If you have any objections, you may disconnect at this time. At this time, I will now turn the meeting over to Miss Sophia Glinos. Miss Glinos, you may begin.

S. Glinos — Thank you and good afternoon. This is Sophia Glinos speaking to you from the Wadsworth Center, New York State Department of Health, located in Albany, New York. Welcome to our teleconference. The 2005 regulatory updates for packaging and shipping diagnostic specimens and infectious substances.

After the program, each participant needs to register and complete an evaluation form. Documenting your participation helps us to continue to

bring high-quality training programs in a variety of formats. The instructions to do this were in the original confirmation letter and the general handout. They were also e-mailed to each site rep this morning. If you don't have the information, you can go to www.phppo.cdc.gov//phtnonline/. The password is packaging. Again, the address is www.phppo.cdc.gov//phtnonline/, and the password is packaging. You'll have until March 24th to complete this process.

If time permits, the end of the program will be opened up for questions. You are on a listen-only line; we cannot hear you, you can only hear us.

Again, welcome and thank you for joining us. We have over 379 sites from across the United States listening today. Today's speaker is Dr. Patricia Payne, who speaks to us from Lexington, Kentucky. Dr. Payne is a clinical laboratory scientist with a doctorate in microbiology. She was appointed to the research participation program at CDC to develop training materials on transportation regulations related to division 6.2 hazardous materials. She has done trainings and meetings sponsored by DOT, IATA, and USPS to remain knowledgeable of regulatory issues. She's presented several workshops throughout the United States that are supported and powered by the Oakridge Institute for science and education

through an inter-agency agreement between the U.S. Department of Energy and CDC. It's my pleasure to introduce to you all, and welcome our speaker, Dr. Patricia Payne.

P. Payne Thank you, Sophia, and good afternoon to all of you online. As Sophia mentioned, I'm going to cover the regulatory changes that affect shipping and packaging that started this year in 2005, January 1st.

Let's get started on slide two. This photo shows some of the numerous materials that are available, that provide either guidelines for shipping and packaging hazardous materials, or helping understanding those guidelines. For those of you who have been involved in packaging and shipping over the past three years, you know that there are a variety of regulatory agencies, which regulate the transport of these materials.

Although I want to focus on the current year's regulatory updates, I would like to take a little time here at the beginning to review how all of the agencies are inter-related, in the hope that it will provide some understanding as to why revisions occur and why the regulations aren't currently standardized.

Slide three: Generally, the regulations are a result of recommendations that originate from the U.N. Committee of Experts. Those recommendations are then published as model recommendations that apply globally to the transport of dangerous goods.

In the U.S., we refer to the dangerous goods as hazardous materials. Each year, the U.N. Committee meets, but they meet periodically. Every two years they then issue amendments. The amendments that are issued are generally in response to either safety concerns or technological advances that have occurred during that time-period.

Governments and International organizations that are concerned with the regulation of the transport of hazardous materials, review those recommendations, and then they consider which ones they will incorporate into their own regulatory documents.

I've tried to capture the flow of information on this diagram that's on this slide. Here in the U.S. we see the recommendations in the form of guidelines from four different government agencies, which are depicted by the acronyms on the lower-left side of the slide.

Although I suspect that all of you are familiar with these acronyms, let me review them: From left to right, at the bottom left of the slide, DOT stands for the Department of Transportation; USPS is the U.S. Postal Service; CDC of course, is the Centers for Disease Control and Prevention, and OSHA represents the Occupational Safety and Health Administration.

On the bottom-right hand of the slide is the acronym IATA, which is for the International Air Transport Association. Most of the materials that we ship by air are sent on carriers that belong to IATA. Although DOT doesn't enforce IATA regulations, Fed EX, DHL and commercial air carriers such as Delta will refuse shipments that are not packed according to IATA's guidelines.

It's relatively easy to develop a standard protocol for shipping and packing if you only use one mode of transport, such as air. However, if you sometimes mail specimens or use a courier, or maybe a taxi for delivery, it becomes a more complicated matter to comply with all the different regulatory guidelines, as there are currently some slight, but significant differences that can affect either the transport of your specimens or the cost of shipping.

In part, the cause of all the confusion involved in keeping track of differences, there is now an effort to harmonize the regulations. As you can imagine, the process of reviewing the U.N. recommendations and incorporating those changes into regulatory documents is slow. Government agencies generally require more time to make changes than professional organizations such as IATA, because government changes must go through legislative review, and be incorporated into law.

For that reason, not all of the current changes that have been recommended by the U.N. in the 13th revision of model recommendations have been incorporated into the regulations of the five agencies that are listed on this slide.

Slide four: I'm going to focus today on DOT and IATA revisions, because as of January 1st, these are the only two of the five agencies that I've mentioned to have regulations that differ from those that they published last year; at least regulations that affect diagnostic specimens and infectious substances.

The DOT changes were published in the Federal Register at the end of 2004. They are accessible electronically and the cover of the federal

register publication is shown on the left side of the slide. The Dangerous Goods Regulations are published yearly. The 46th edition of the IATA DGR is shown on the right. It became effective January 1st of this year, and it will be effective for the entire year.

Slide five. Let's start with a change that's consistent between both agencies. Shown here, is the air eligibility marking. Unfortunately it was never a requirement to use this; it was an option that was being considered as a requirement by both IATA and DOT last year. This year, reference to the use this marking has been completely removed from both regulations. However, any packaging that contains this marking can still be used and it's not considered out of compliance to put that marking on a package.

Slide six: Part of the reason that the use of the air eligibility marking has been dropped, is that an additional statement is now required for hazardous materials shipped by air. As of January 1st, the statement circled in red, "I declare that all of the applicable air transport requirements have been met", must be included as part of the certification statement that is pre-printed at the bottom of the red candy-striped shippers declaration form, which we all use when we're transporting by air.

DOT s allowing that segment to be used immediately, but it's not enforcing compliance until October 1, 2006. Those hazardous materials that are transported by air are almost exclusively transported by IATA members; add this statement to all declaration forms in use now.

I've already heard that Fed EX is returning packages that are not in compliance with this regulation. So let me just reiterate this: this statement is required by IATA, but if it isn't on the bottom of the shippers declaration form of a package being sent, say for instance, by Fed EX, it will be returned to you.

Next slide, slide seven. You don't need to toss all of your old shippers declaration forms. If you have a form that was printed before January 1st of this year, you can add that new statement at the end of the old certification. The new certification statement was printed and read on this slide for emphasis. It is not required to be in red or any other colored format.

Slide nine: a second option is to add this statement, as shown here on this slide, in the additional handling information box. Slide nine: another marking that is changed between both agencies is the over pack marking.

The statement shown on the upper-left side of this slide, inner packages comply with prescribed specifications was previously required by both IATA and DOT on over packs that concealed U.N. specification packaging. Affective January 1st, only the word, "over pack", is required to be used on packages whose markings and labels are not visible through the over pack.

DOT will allow the use of either the word over pack, or the statement in the left upper-hand side of this slide, until October 1, 2007. At that time, only the word over pack is acceptable for DOT shipments. If you ship by different modes of transport, it may be less confusing to just totally ship and switch to using only the word over packs for marking all shipments.

Slide ten: IATA is now recommending that security awareness should be included as part of Hazmat training. This recommendation shouldn't have any impact on your training, as it's already a requirement by DOT. To be in compliance with DOT regulations, security awareness training must be a part of all new Hazmat employee's training, or their recurrent training that is provided after March 25, 2003. Therefore, as of March 24th next year, in 2006, any type of training that you give must include security awareness training.

I haven't included security awareness training in any of the courses I've conducted, because each facility ships different types of materials. Also, I'm not aware of any training companies that include that in their initial or recurrent courses. However, the Department of Transportation has developed a training module on security awareness, a CD ROM that they developed, is for general use in the Hazmat industry. It's not specific for shipping diagnostic specimens, or infectious substances. However, DOT states, that if you complete this training module and the CD ROM and the included interactive test, this will meet the general awareness training requirements for all Hazmat employees.

Therefore, if you don't want to develop a security awareness training specific for your institution, or until you have time to develop that training, this is a free and easy method of meeting that requirement. The cover of the CD ROM is shown on the right of this slide.

Next slide, slide 12: I told you that this security awareness training module is free, and you can order it from the DOT Web site, hazmat.dot.gov, by clicking on the blue diamond shown here, that is labeled e-hazmat online purchase and payments. From the page that opens, follow the link to free publications. It's not copy write protected, therefore if you have multiple

facilities, you can copy it and share it as needed. If any of you check the DOT Web site regularly, you'll see that they've changed their home page in the past three weeks. However, all of the links on that page are still functional.

Slide 12: This is an advanced warning of a change in the format of the shipper's declaration. It will not officially change until January 1st in 2007. The change will be to the format shown on this slide. The U.N. number will become the first sequence of information, followed by the proper shipping name, and then the hazard class and the sub-risk, if it's applicable. Until then, it's permissible to use either the new format shown here or the old format, which has the proper shipping name listed first.

Slide 13: Now for the big change. Following the U.N. model recommendations, IATA has completely revised the classification of infectious substances, and biological products, to remove all references to risk groups. The definition of an infectious substance is unchanged. It is still defined as a substance, which is known or is reasonably expected to contain a pathogen. In place of risk-group assignments, now infectious substances are divided into two categories, either category A, or category B.

The next slide, slide 14, shows the difference or the definition of a category A infectious substance. A category A infectious substance is any substance that is transported in a form that is capable of causing a permanent disability, life-threatening or fatal disease upon contact with a human or animal, if it's released outside the packaging used in transport. So, a category A infectious substance includes pathogens that are highly infectious and easily transmitted when in large concentrations, such as in a culture. A category A substance could also be a tissue, or some type of human or animal material that contains a pathogen, which is highly infectious upon contact, even in small amounts.

We identify category A infectious substances by the proper shipping name, infectious substance affecting humans or infectious substance affecting animals, as appropriate. No changes from last year, you use the U.N. number 2814 for those affecting humans and U.N. 2900 for those affecting animals.

Next slide, slide 15: A list of indicative examples of category A substance is given in the 2005 edition of the Dangerous Goods Regulations. It's found in table 3.6D. Many of you are going to recognize those listed as infectious substances affecting humans, those that are assigned to U.N.

2814. This is the same list that was found in the IKO Interpretation and Guidance Document of 2003.

In that document, which was affective until the end of last year, the organisms were listed as indicative examples of infectious substances that should never be classified as diagnostic specimens in any form, unless otherwise indicated. If you ship materials by air, be aware of this regulation and check the DGR. As shown here, some microorganisms, such as the top-four listed on this slide, Bacillus anthracis through micro bacterium tuberculosis are category A substances only if they're transported as cultures. Others, such as Ebola, Monkeypox, and Variola viruses are classified as category A infectious substances, if they're transported in any form, including in a patient's specimen.

This slide does not show the complete list of microorganisms that are category A infectious substance. Even the table in the DGR is not a complete list; it's an indicative list. A microorganism whose identity isn't known is assigned to this category based on patient's symptoms, known medical history, endemic local conditions, or professional judgment. If there is any doubt whether an unknown microorganism meets this category, you must assign it to category A.

If you're transporting a clinical specimen that might contain one of the micro-organisms on this list that do not have culture-only beside it, also classify that specimen as category A. New or emerging pathogens, which meet the same criteria as microorganisms on this list, must also be assigned category A.

Slide 16, next slide: Category B infectious substance is defined very easily. It's an infectious substance that doesn't meet the criteria for inclusion in category A. This includes human or animal materials, such as excreta, secreta, blood, tissue, and body parts, what we called last year, diagnostic specimens. It also includes cultures of microorganisms that are not identified or indicative of those listed in the table 3.6D.

We're going to use either diagnostic specimen or clinical specimen for the proper shipping name of a category B, infectious substance, and assign then to U.N. number 3373.

Before we move to the next slide, I want to emphasize, that classification into category A and category B infectious substances is currently only in the IATA regulations. Therefore, if you send packages according to DOT regulations, don't use the proper shipping name, "clinical specimen".

Next slide, which is slide 17. Use packaging instructions 650 for the transport of category B infectious substances, which again were going to be identified as either diagnostic or clinical specimens. This year there are few changes to those packaging instructions, and I've highlighted those changes in yellow on this slide.

The maximum amount allowed in a primary receptacle has increased. Receptacles containing liquids can now hold up to one liter. Receptacles containing solids can hold up to four kilograms, which is also the maximum amount for the entire package contents.

Specimens can now be packed with up to 30 milliliters of a preservative, without declaring that preservative as a hazardous material, only if that preservative is a class 3, 8, or 9 hazardous material. Examples of those type of preservatives would be methanol and ethanol, which are class 3 hazardous materials and solutions of formaldehyde that are 25% or more, which would be classified as a class 8 hazardous material.

I can't think of a class 9 hazardous material, other than dry ice, which could be used as a preservative, but there may be one. However, don't

misconstrue this slide. You're never supposed to place dry ice inside either a primary receptacle or a secondary container.

Another change in packaging instruction 650, is that the outer packaging is now specified to be rigid. Manufacturers must now provide instructions for filling and packing boxes used for the transport of diagnostic specimens, or U.N. 3373 substances. It's the shipper's responsibility to follow those instructions. If your facility requires that patient ships specimens to you for testing and you provide materials for packing and transporting, you must now provide clear instructions to the patient on filling and closing those packages. The regulations don't define what clear instructions are.

However, it's possible, depending on your clientele, that you can provide a copy of the original manufacturers instructions, but depending on your clients, you may need to re-write those into a more user-friendly format, or possibly you may even need to translate it into a different language for non-English speaking patients. I want to emphasize that this slide highlights the changes in packing instruction 650. It isn't a complete outline of those instructions.

Now we're going to move to slide 18. Besides the proper shipping name, which we put on the package last year, the outer package must now contain a U.N. 3373 marking. The U.N. marking is a square on end or a diamond that has equal sides enclosing the text U.N. 3373. The marking should be adjacent to the proper shipping name, which is either diagnostic specimen or clinical specimen and on the same side of the package, if the dimensions of the package are adequate. If you're hand-drawing the marking on the package, you need to refer to the packing instructions for specifics of the dimensions of the diamond and the size of the lettering that is required.

Also new this year is a requirement for the name, address, and phone number of a responsible person, to be indicated, either on the package or on the air-weigh bill. The regulation does specify who has to be listed as the responsible person. However, make note that this is a slightly different notation, than that required for infectious substances. Infectious substances do not require the address of the responsible person to be listed. Also for an infectious substance, the responsible person marking must be on both the package and the shippers declaration form.

The box on the right of this slide is probably marked according to packing instruction 650. Notice that I used the proper shipping name, "clinical specimen." It's also correct to use, "diagnostic specimens", as the proper shipping name. I chose to label the package with the responsible person information, but I could correctly have omitted that from the package and put it on the air-weigh bill instead. It is not required to be on both. If you routinely ship both infectious substance and diagnostic specimens, you may find that is useful to just adopt a standard protocol and always place responsible person information on either the package or the paperwork for diagnostic specimens.

Let's move on to slide 19. As was required last year, the air-weigh bill that accompanies a diagnostic or clinical specimen must include the proper shipping name. This year, in addition, you must add the U.N. number, U.N. 3373 and the nature and quantity of goods boxed of the air-weigh bill. You only need to mention the responsible person, name, address, and phone on the air-weigh bill if you're not placing it on the outer packaging. As each carrier has a different format for air-weigh bills, check with your carrier to determine the preferred location for putting the proper shipping name on their form.

I suspect that eventually the companies will change their air-weigh bills to include all of that information and we'll just be checking a box in the future, but until then, a phone call to your carrier may prevent returned packages.

Slide 20: You still use packing instruction 602 for category A infectious substances. There aren't many changes to these instructions this year. The instructions no longer state that screw caps must be re-enforced with adhesive tape. Instead, the instructions state that if screw caps are used for primary receptacles, you must secure them by some positive means, such as tape, paraffin sealing tape, or manufactured locking closures. As for packaging instruction 650, outer packaging is required to be rigid.

Slide 21: The regulation requiring advanced arrangements between the shipper and the operator has been removed. The shipper is no longer required to phone, fax, or electronically notify the recipient of a category A infectious substance shipment. Therefore, the notation prior arrangements as required by IATA DGR 1.3.3.1 have been made, is no longer relevant, and you shouldn't include it in the additional handling box on the shipper's declaration form.

Next slide, and this should be slide 22. We still have to use U.N. specification packaging for materials packed according to 602. The outer package should be marked with the appropriate proper shipping name and the appropriate U.N. number. However, for IATA, as of January 1, the technical name is only required to be used for documentation. Therefore, you do not have to record this on the outside of the packaging. The package shown on the right is correct and it's marked for shipping category A infectious substances. So other than the omission of the technical name, there are no differences on the markings this year than from last year.

Next slide, slide 23: special provision A140 is a new provision. It re-enforces the use of the technical name only on documentation. Further, the provision allows us to use a new phrase, "suspected category A infectious substance", in place of the technical name, when the identity of the material being shipped is not known. As shown here, place the phrase inside the parenthesis in place of a specific technical name. Do not put the special provision number A140 in the authorization column.

When you use the phrase shown on this slide, also included as part of the proper shipping name on the itemized list of contents that's enclosed

inside your outer packaging. I showed one format here, but you can use this same information in the second format of the shipper's declaration.

Next slide, slide 24: The wording of special provision A81 has also changed. Prior to January 1st, A81 provided relief from quantity limits listed for either passenger or cargo aircraft for body parts, organs, or whole bodies, and for body fluids that might contain infectious substances if they were transported in primary receptacles containing no more than one liter of material.

Since the quantity limits for the liquid infectious substances is now been increased to one liter per primary receptacle, A81 has been revised. The text of A81 is shown here. It now applies only to body parts, organs, or whole bodies. Of course, they should be packaged properly, which is not necessarily characterized in this photo. When you use the special provisions for transport, it must be noted in the authorization column of the shippers declaration form.

Slide 25: There are other changes in the 2005 edition of the DGR, but I didn't believe that they directly pertain to the transport of either infectious substances or diagnostic specimens. So I haven't included them in this

presentation. However, if you are concerned about all of the regulations, you can gather more information on dangerous goods transport directly from the IATA Web site. The URL for it is shown here at the top of this slide, and I captured the page on this slide.

On the right-hand side of the Web page, under the heading, “In the Spotlight”, which is encased in the red square, there are links to pages that contain the agenda to the 2005 regulations, checklists for non-radioactive shipments, checklists for dry ice, and a copy of packing instructions 650. Prior to this year, you cannot receive any packaging instructions without purchasing a DGR.

If you want to purchase a copy of the DGR in order to have complete access to all the regulations and to packaging instruction 602 and packaging instruction 904, which you use for dry shipments, you can find that information on this Web site.

Slide 26, next slide: DOT still allows us to use IATA packing instructions for air transport of division 6.2 materials, but DOT hasn’t changed any of the information in the hazardous materials regulations that pertain to either classification or packaging of those materials. They did publish a final

rule in December of last year that contained the revisions to the over packs markings and the upcoming revisions to the shipper's declarations that I mentioned earlier.

However, within that document is the statement that is shown on the right, says this slide, and then I circled in red, and that statement says, "amendments to the HMR, related to infectious specimens, will be addressed in the future", and it's specifically going to be in a world-making docket HM226A. Therefore, expect some changes to occur sometime in the future.

I don't have any information to share on when those proposals or when the final rule might be published, but we will all be watching for it, because the assumption is they are going over the U.N. recommendations and considering which, if any, that they want to incorporate into the HMR. There is a big effort to harmonize all these regulations, so I would suspect that most of them will be incorporated, but again, I don't know until they're published, which ones will be.

Slide 27: So in the interim, I summarized in this table, some of the current differences between DOT and IATA, and then I threw in the postal

service, even though they haven't made any changes, many of us use the mail for shipping our packages. So on this slide as a summary, are some of the differences for diagnostic specimens. As you see in the second column, the quantity limits are less for DOT and the mail, primary receptacles can only contain up to 500 mils or 500 grams, when you're using those two agencies regulations, but we're allowed one liter for a primary receptacle containing liquids for IATA and up to four kilograms for solid specimens.

Currently, only IATA specifies that a diagnostic specimen package should have one dimension being at least four inches. When you go over to the last two columns on this slide, you see markings on outer packaging. Only IATA allows the use of clinical specimens as a proper shipping name. IATA requires the proper shipping name on both the package and the air-weigh bill. The U.N. 3373 diamond marking is only required by IATA; it's required on the package. The U.N. number is required on the air-weigh bill. Responsible person information includes an address and is up to the shipper to determine whether it should be noted on either the package or the air-weigh bill.

Next slide. The packaging instructions for infectious substance are still very similar between all the agencies. There are no differences in quantity limits for air transport between either DOT, the postal service, or IATA. The quantity limits for all packages sent by mail, continues to be 50 mils or 50 grams and cargo-only packages are not allowed in the mail. Continue to use the technical name on both documentation and the outer packaging for specimens that are being transported under DOT or postal service regulations. If you need to use the new statement, suspected category A infectious substance, use that only for a technical name on the documentation for IATA shipments.

Consult table 3.6D to determine if a microorganism or a culture of a microorganism must be assigned to category A. Remember when you use DOT or postal regulations, your classifying specimens according to risk-groups and all cultures of risk-group 2, 3, and 4 micro-organisms must be shipped as infectious substance and assigned to U.N. 2814 or 2900 if you are using DOT or postal regulations.

Next slide, slide 29: If you've been shipping for the past few years, you are undoubtedly aware that the revisions to the dangerous good regulations can occur after the DGR is published. Those revisions are generally

published as an addendum, but they are not automatically sent to everyone who purchases the DGR. The addenda are posted to the IATA Web site, which is the first URL shown on this slide. From that Web site, you can link to all the downloadable information that they provide for free. So that's going to be addenda, checklist, and the diagnostic specimen packing instructions.

If you have a specific question on interpreting their regulations, you can contact their dangerous goods hotline. You can contact them by phone, by fax, or e-mail, and I put that information on this slide. I've used the e-mail quite often for questions and I liked that, because I then have their reply in print, that I can file away for future reference, but I have called them and until very recently, I received very quick answers by phone call, but in the past few weeks they've been referring me to e-mails. So I'm not sure if they're just overworked or if they prefer e-mail questions.

There's also a dangerous good communications mailing list that has started within the past probably six months, and if you subscribe to that mailing list, you will receive by e-mail information on key issues, addenda, or any changes that are coming up that relate to all hazardous

materials. You can check the URL above and find information for signing up and joining that mailing list.

Next slide, which would be slide 30: There are several government Web sites that provide information about the federal register and the rules that are published on it. I find that the Web site listed here: hazmat.dot.glb, is probably the easiest to navigate. From their home page you can follow the rules and regulations link and you can ultimately find an updated list of proposed and final rules, under the heading, "Rules Making and Federal Register Notices." If you want to bookmark that, that's a good place to find out when any changes are going to come about that might affect infectious substances. That's when that docket HM226A will be posted. Their hotline is very useful for questions specific to the regulations, but don't expect to receive any information from that hotline concerning when any proposal rule making is going to happen.

There is another method for submitting questions by e-mail, and that information is on their Web site. I don't have any personal experience about submitting questions by e-mail. I do know that their information hotline is manned throughout the week and people are very competent in answering your questions right away, or getting back to you.

Next slide, slide 32: Although there aren't any changes to the postal regulations currently, I thought I would include their Web site for completeness. Public Service Web site isn't the most user-friendly, but once you understand it, it's easy to navigate and you can access all of their, like regulations. I want to make a cautionary statement about the postal regulations. Their regulations are law, as are the DOT regulations, and they are published in the Domestic Mail Manual, which you can access from this Web site. Publication 52 is a postal service publication that is still accessible from this site and from many other sites. It contains easy-to-read packing instructions for diagnostic specimens and infectious substance.

Pub 52 is not a regulatory document, and a statement in the front tells you that you must refer to the Domestic Mail Manual for the regulations. Pub 52 was published in 1999. At that time, it had the same information that was included in the Domestic Mail Manual, now that information isn't current. It is being revised, but right now it's not current. So if you are using information from publication 52, please replace it with the regulations that are now found in the current edition of the Domestic Mail Manual.

That is all the information that I have today on the new revisions, the ones that I'm aware of, that have just changed, and at this time I would like to turn it back to Sophia and I thank you for your attention. I hope you find that this information is useful.

S. Glinos Thank you, Pat. I think it was a great, great presentation, and we have some time for questions. Mike, if you want to open it up?

Coordinator Thank you, at this time we are ready to begin the question and answer session. Our first question comes from Nebraska. Your line is open; you may ask your question.

W Yes, slide six, where it says, I declare that all applicable air transport requirements have been met, I'm a little confused where that needs to appear, and on which type of assessment, diagnostic or infectious, or both?

P. Payne Okay, that certification statement is only on the shippers declaration, which is only required for infectious substances, and you will put it, if you look at the following two slides, slide seven and slide eight, you can put it in either of those locations, and it is correct.

W Thank you.

Coordinator We have another question from another Nebraska location. Go ahead, your line is open.

M Yes, would you have to ship E. coli that's non-infectious as a diagnostic specimen?

P. Payne Would you have to ship E. coli that is non-infectious as a diagnostic specimen? Is that what you're asking?

M Yes, Ma'am.

P. Payne I don't know exactly what you mean by E. coli that is non-infectious, but I will answer your question in what I think you are asking. E. Coli is not on the table, 3.60 indicative list as a substance that must be kept classified as category A by IATA. Therefore, if you have a culture of E. coli, or a specimen that contains E. coli, it does not have to be a category A infectious substance, and I'm talking about E. coli, generic E. coli, all right? Now, if you are sending that, not by air, you will be following either the mail, Domestic Mail Manual, or you will be following DOT

regulations, and if it is a culture of E. coli, you would have to send that as an infectious substance.

M Okay, thank you.

Coordinator Thank you. Next we have a question from Indiana. Your line is open, please ask your question.

W Yes, my question is on the packing instruction 650 markings, where you describe the rectangle with the U.N. 3373. Is it acceptable to use the stamp instead of that – instead of a stamp just being a rectangle and not meeting those requirements, or is that requirement for the rectangle with the U.N. 3373 strict?

P. Payne Okay, I'm not sure exactly everything you asked me, but let me restate it. The requirements for using the diamond, which I'll call a square on end, with U.N. 3373 are strict. You must put that on the package; it's a marking. So as a marking, it can be hand-drawn, it can be stamped on the package, it can be a label applied to the package. Within the packing instruction 650, there are very specific requirements on the minimum size of that square or that diamond. There are also very strict requirements on

the minimum size of the lettering, and I don't have that right in front of me.

W So, you're saying that it's just a stamp saying that this package meets U.N. requirements 3373 is not acceptable?

P. Payne That's right. That is not acceptable. That was an old stamp, I think from two years ago. I think what you are talking about, is part of the original information that said diagnostic specimens packed according to IATA packaging instruction? Is that what you're talking about?

W That's right.

P. Payne Right, that I can't say regulatory wise, if that was still on your box, it should not be returned to you, but if you don't add that diamond with U.N. 3373, it is now not in compliance.

W Okay, and my second question is, is an air-weigh bill required only on infectious substances? That is, can you eliminate the air-weigh bill if you just have diagnostic specimens?

P. Payne The air-weigh bill is only used if you're sending things by air.

W Diagnostic specimens by air?

P. Payne By air. You would only use an air-weigh bill if you were sending something by air. So if you're going Fed EX, if you're going DHL, UPS, I'm trying not to leave anybody out.

W Is that the same as their bill, and is that the same as their transportation bill, the air-weigh bill?

P. Payne I think they all say air-weigh bill on them, but to be honest with you, I don't have that off the top of my head, but it's their transportation forms that you send with the package and I didn't include a format, because I've seen them and they're all different, and even though the regulations state, put in the nature and quantity goods box of the air-weigh bill, I've actually never seen an air-weigh bill that has what they call nature and quantity of goods boxed, although I do know that, they do have places for you to mark if the specimen, at least Fed EX has a place to mark, is this a dangerous goods, yes or no.

So that's why and when I've called them, it depends on what area of the country you're in, where they ask you to put the diagnostic specimen, and some companies don't care where you put that proper shipping name, as long as it's just on the air-weigh bill. So it's regulatory requirement now that, both the proper shipping name and U.N. 3373 be included on the air-weigh bill, but it is not stated where it has to be. I think it is just easier if you call your carrier, find out where they want it and then you don't have packages returned.

W Okay, and you don't need a shippers declaration for diagnostic specimens, is that correct?

P. Payne No, I did not intend to give you that information. If I've misstated that, I apologize. Shippers declarations are only required for infectious substances.

W Thank you.

Coordinator Thank you, and next we have a question from Wyoming. Your line is open. You may ask your question.

W Hello, regarding the responsible person, could you tell us if the responsible person can be listed as an institution, say a community hospital, or if it actually has to be the technologist or the shipper, the person who shipped the item, and I mean packaged it?

P. Payne I don't think that – that I know, that is not specified within the regulations. I do know, that for infectious substances that a responsible person is actually a person that they want to contact. So it is an individual. I have heard second-hand, third-hand, fourth-hand, that some carriers want the responsible person to be either the shipper or the recipient, but that is not stated in the regulations, and here we go back into that old problem that some of us have had, we're following the regulations, but our carrier wants us to do things a little bit differently.

So I think the best thing to do – one, I would never put, like an institution, I would put a name, because they're asking specifically for a name, address and a phone number. So that phone number needs to link to a person. That's the best I can tell you. It is not specified within the regulations, since it's a requirement of air transport only at this time, I would ask your carrier and I would just follow their recommendations, because in that manner you won't have a package returned.

W Thank you.

Coordinator Thank you, and next we have a question from Missouri. Your line is open, please ask your question.

W Hi, could you explain the difference between IATA regulations and DOT, and when it's appropriate to use each. If we're shipping in the United States only, can we just choose to use DOT regulations?

P. Payne Yes, a very simple answer. If you're shipping within the U.S. and you choose to use DOT regulations, that is permissible. However, if you're shipping with Fed EX, UPS, GHL, or maybe you're shipping things by an air carrier, such as Continental or Delta, they're an IATA member, and they will not accept anything that is not packaged according to IATA.

W Okay, thank you.

Coordinator Thank you, and next we have a question from Illinois, your line is open, please ask your question.

W Yes, I was wondering what the difference is – this seminar does not certify individuals, what would constitute certification?

P. Payne To be certified, one, you have to take a complete training. You have to meet all of the training requirements that are listed in the regulations. That includes information on familiarization with the regulations, realizing that there are different classes of hazardous materials, realizing that you might be shipping something as part of your infectious substance or diagnostic substance packaging that includes another hazard class, and if you do, where do you go to find those packing instructions.

It also requires that, if the training is specific for your job, therefore, if you are a person who always packages, then you just need to learn the packaging information. In some facilities there are people who classify all the specimens and pass that off to someone to package them. So the training required is specific for your job function.

If you're a secretary and you're filling out the shippers declaration, you're required be trained and you have to be trained on whatever your function is. So if you're filling out the forms and you're also classifying, you need to understand all of those regulations. Included in that training is the

requirement of safety. Almost all of us have OSHA training as part of our job requirements, and that covers handling blood-born pathogens and infectious substances. So that training qualifies as part of the training for shipping hazardous materials.

W But there is not a company that per say, certifies you?

P. Payne Well, you know, the regulations state that your employer certifies each employee, and the reason – you could come to a training and they could give you a certificate after words that says you are certified, but the regulatory – DOTs, our regulatory group, they are counting on the employer to state that they certify, that any training you received, whether it's from them, or whether it's from an outside agency, it's sufficient for your job, and the reason for that is, only your employer knows what's specific for your job function.

W Thank you.

Coordinator Thank you, we have a second question from Illinois. Please ask your question.

W Are the orientation arrows on the sides of the boxes still required?

P. Payne The orientation arrows are required if you are shipping a liquid specimen and in the regulations it states, of 50 mils or more. Think there just preprinted on everything, and if you put it on a package that doesn't have as much liquid as necessary, that's fine. It's just – for most of us, we don't ship specimens of four liters, but it's required on all hazardous materials, not just clinical specimens that are liquid. Did that answer your question?

W Yes, thank you.

Coordinator Thank you. Next we have a question from Pennsylvania. Please ask your question.

P. Payne I'm sorry, I didn't hear that.

W The question pertains to shipping with dry ice. You said the dry ice could not be in the primary or the secondary container. Could you give me a scenario starting with the specimen of appropriate packaging with dry ice?

P. Payne You want me to give you – I can barely hear you, I'm sorry. You want me to give you an example of a specimen that would-

W No, you said that dry ice could not be present in the primary or secondary packaging, and I'm asking for a scenario, starting with the specimen, appropriately in its container, how would you package it for shipping when you use dry ice? How many stages or layers, and where does the dry ice fit in?

P. Payne Oh, the dry ice is always outside the secondary container. So it will be in the outer packaging, around the secondary container. So let's assume you're sending a frozen specimen, a tissue that's frozen, that's in a primary receptacle of some type. That is placed inside another container, which is referred to as the secondary container, and then you wrap your itemized list of contents. I'm assuming this is infectious substance, it could be something else, and it could be a diagnostic specimen. You put your itemized list of contents outside that and you would set that in a box that contains dry ice.

W Thank you.

Coordinator Thank you, next we have a question from New Jersey. Your line is open, please ask your question.

W Our question refers to the ground transport of cultures on auger plates, with the knowledge that they do not need the specifications for primary container. Is there any way they can be placed inside another container, say for example a leak-proof zip lock bag before being placed in a secondary container, and transported by ground?

P. Payne I can try to answer that. Boy, what a sneaky question, that doesn't have to do with revisions, but let's go over it. You're asking me if you can put, for instance like a Petrie dish?

W Yes.

P. Payne In a zip lock bag and send it by ground?

W And then in a secondary and an outer package as per the regulations.

P. Payne Which regulations are we talking about?

W DOT

P. Payne The primary container needs to be sealed, and I don't want to be the person who gives you the final on this, but I think if you put that in a – I don't know if you would call it every zip lock bag, but a zip lock bag that is stated to be sealed. So we're not going out and buying Glad bags, but we're purchasing from packaging companies, sealable bags that are stated not to leak. Then all of that together becomes your primary receptacle, and that meets the requirements.

Now, if you're going by courier and you know that people are handling it correctly, because of course now this still has to be packaged as an infectious substance according to DOT regulations, then you would want the package upright, so that if it gets turned over, the Petrie dish isn't opening. I think you would want to work with the person at the end, and you may be receiving something from a satellite clinic, so you're the person who opens it at the end, but the reason behind this regulation is, that you don't want to open even a zip lock bag that now has the contents of a Petrie dish falling outside the bag.

In regulatory rules, it just states, the primary receptacle has to be sealable and it is common knowledge that a Petrie dish is not sealable. So I think you would be skirting, maybe the issue a little bit to do that, but I don't think it's impossible for you to package a Petrie dish in a safe manner, in a zip lock bag, but I'm not sure any person who came in to inspect you would agree with that, because there is that chance that it would fall out in your bag.

W I have a part two to this question. Part two is, certain agents of government, federal, state, and local, and health and law enforcement, would then be exempt carriers of – can be exempted from the HMR, is that correct?

P. Payne I didn't mention that again. This is another one of those questions. That is in the DOT regulations, that government agencies who are transporting hazardous materials within their line of work are exempt from the regulations. If they are using Fed EX or any commercial carrier, they are not exempt.

W Can we use the government agents to transport the auger plates?

P. Payne That is allowable within the regulations. If you are a government agency, you are exempt from those regulations.

W Thank you.

Coordinator Thank you. Next we have a question from Minnesota. Your line is open, please ask your question.

W Yes, this is another sneaky question that you didn't cover. The DOT language talks about when you use a private courier transporting a diagnostic specimen, then you are exempt from DOT regulations. So my question is, what about when you are using a private courier with a substance that meets the definition of an infectious substance. Are you still exempt from the regulations?

P. Payne So let me make sure I'm answering your question correctly, so I'm going to restate it. You are transporting an infectious substance, am I correct?

W Correct.

P. Payne Infectious substances are never exempt from any regulations. So no matter how you are transporting them, it doesn't matter whether you are transporting them in what they call, designated vehicles, that exemption is only for diagnostic specimens; it is not for infectious substances.

W So if you were transporting an infectious substance from one hospital in your town to maybe a clinic across town, you would have to fully package it in a fully certified infectious package including the shippers dec?

P. Payne My explanation is going to beyond answering here, but I can answer that by e-mail. The simple answer is, yes, you have to put it in a complete U.N. specification package and the specific answer is, within the DOT regulations, there are some, by the description that you're explaining it, so you're driving it, its surface, it's in town and depending on if you're the person who actually owns that package from beginning to end, you may not have to put all of the addresses on the outside, and DOT doesn't require that candy-striped shippers decoration that we automatically think of.

So you can get a round the – you still have to put most of that information on some kind of form, but you wouldn't have to necessarily fill out a

complete form each time. You could have more like a shipping manifest and use it. Okay?

W Okay, thank you.

Coordinator Thank you. Next we have a question from California. Your line is open, please ask your question.

W Yes, I have a question and I hate to beat this dead horse. With regarding the responsible person, name and address. I understand it can't be an institution, but is that for the person sending it is to receive it, or the person that's mailing out? A second question with regards to the secure locking for screw caps. Can you give me an example of a manufactured locking closure?

P. Payne Let me try to answer the first one first, and now I totally forgot what you asked me. Let me answer the second one. The manufacturer closure: there is some primary receptacles that have little tabs on them, that lock over, so that you know that you've screwed it completely closed, and they won't lock until you've reached the point that it's totally closed.

Manufactured closures in research settings, I see back seams. Some liquid specimens coming with the metal seal on the top. I'm sorry?

W Can you repeat that please, I can barely hear you?

P. Payne There are some containers, where you can use metal closures on top, but they're usually applied by the manufacturer, okay? They're metal containers, you can insert a syringe and put something inside that container, but because there's a metal seal around the outside, the top doesn't pop open. That would be an example, and I'm sorry, but I've totally forgotten your first question. What was it?

W Earlier we were discussing the responsible person, name, address, and phone that we include on packaging?

P. Payne Right.

W I understand that you cannot send that to an institute. However, I guess my question really is, is the responsible person the person that's sending it or is the responsible person the person receiving it?

P. Payne The regulations don't specify who the responsible person is. So it could be either. It's actually the person that, if there's an accident and that package breaks open, it is the person who would want to know that and would be able to address any clean-up questions. So they would know what was in the box.

W So basically then, it would be preferred that it be the person sending it?

P. Payne I would think in most instances, the shipper would be the person who knows that, but again, I had a couple of people call me and tell me that, their specific carrier stated the responsible person must be shipper one time, recipient another time. So I think the best thing to do is call your carrier. If you use a specific carrier, and ask them, do you have a recommendation, do you have a requirement that we use one or the other, because the regulations do not state who it has to be.

W Okay, great, thank you.

S. Glinos Mike, this is Sophia. We have a couple more minutes for maybe a couple questions. I just want to – I know all the questions are important, but we would like to try to stick to the changes if there's people in the queue that

might have a question on what we talked about today. So we can take a couple more, and then I'll give everyone some directions on how to e-mail additional questions.

Coordinator — Okay, just one second, I do have a question from Missouri, you're line is open.

W — When you are under the IATA regulation, on category B, we see most of our stuff in that category. Are we supposed to start using U.N. 3373; is it wrong to use the 2814?

P. Payne — If you're sending category B infectious substances, so you're using IATA regulations, you're using packing instruction 650, you will put the proper shipping name on the box, either clinical specimens or diagnostic specimens and you will use U.N. 3373 marking, which is that diamond marking. You will only use infectious substances affecting humans or animals for those substances that are in category A. So basically, the definition of diagnostic specimens that we still use for DOT, which says any human or animal material, that's now included as part of category B, infectious substances. It's not a separate definition; it's included as a

category B infectious substance, as are cultures of organisms that aren't on that category A indicative list. I hope that's clear

W I think so.

P. Payne If you sit down and look at it, it is actually very – it is a much clearer way, because it allows us to send those cultures that are not really a danger to people, if you come in contact with them and so by separating them into category A, which most of us will think are risk-group for pathogens or cultures of things that are highly infectious, such as coccidioides immitis, you don't want spores of that breaking open.

Then you put those all in one category, category A. So category A could be what we consider a patient or a human material, but it's a category A because it includes something that's highly infectious upon contact, such as Ebola. It also includes those infectious cultures, but now category B includes typical, what I'm going to call now, "diagnostic specimens", that might or might not have some pathogens in it and it also includes some cultures, such as E. coli which is going to be infectious if they break open and we come in contact with them during transport.

W Okay. Yes, great.

Coordinator Thank you. Next we have a question from Illinois. Your line is open, please ask your question.

W Yes, I was wondering about the change that occurred last year, when the DOT adopted the IATA guidelines for the 95KPA pressure vesical inside, now if I'm shipping ground transport by a taxi cab, do I still have to buy the boxes that can withstand that air pressure, like for the post office and for IATA?

P. Payne That regulation is only for air transport.

W Not even the post office?

P. Payne No, the post office is different, because if you send anything by first-class mail, that's considered air, and so even though you may only be sending it across town and you know it's not going in a plane from your facility, if it's going by first-class postage or higher, it has to be packaged according to air.

W All right, thank you very much.

S. Glinos Okay, thank you everyone. If your question was not answered, you still have an opportunity to send in your question. You can e-mail that question to neoffice@nltn.org. Dr. Payne will respond by e-mail to you. Again, I would like to remind everyone listening, to register and complete an evaluation form by March 24th. The directions for this are in your confirmation letter and the general handout and they were also e-mailed to each site rep this morning.

Documenting your participation helps us to continue to bring high-quality cost-effective training programs in a variety of formats. When you've completed the registration and evaluation form, you will be able to print your continuing education certificate, and that concludes our program.

The National Laboratory Training Network would like to thank Dr. Patricia Payne. I hope that all of you will consider joining us for future programs and that you'll make the National Laboratory Training Network your choice for laboratory training. From the Wadsworth Center in Albany, New York, this is Sophia Glinos. Thank you.